

REMARKS

Applicant has amended claims 14, 31 and 33, and have added claims 38-42. Claim 20 has been canceled without prejudice or disclaimer. Support for the amendments can be found throughout the application, for example at Table 3 (third row), the paragraph bridging pages 7-8, the last full paragraph on page 9 and the top of page 13. Applicant submits that these amendments overcome the indefiniteness rejections of the examiner. Applicant also provides a third declaration from Dr. Teschner.

The claimed invention is not taught by the prior art

On pages 2-3 of the office action, the examiner rejected the claims as anticipated by or obvious over the '930 patent to Ristol Debart *et al.* This patent is discussed in the latest declaration of Dr. Teschner. Applicant respectfully traverses this rejection.

Dr. Teschner explains that the diafiltration alone approach of the '930 patent will not effectively reduce citrate. The difiltration only approach is described in Experiment 1 of the Teschner declaration follows the '930 patent. Ultimately, this approach only resulted in a 96.6% reduction of citrate and a 97% reduction of aluminum. See paragraph 8 of the declaration.

The approach of the captioned application uses a water-soluble monocarboxylate, a water-soluble dicarboxylate, a monocarboxylic acid and a dicarboxylic acid to replace, and thereby reduce, citrate. Experiment 2 of the

Teschner declaration uses caprylate as an example. The data from Experiment 2 shows that the invention can achieve a 99.9% reduction of citrate and a 99.5% reduction of aluminum. See paragraph 8 of the Teschner declaration.

Accordingly, applicant's invention is significantly more effective than the approach of '930 patent.

Applicant submits that the '930 patent cannot anticipate or render obvious the claims because the '930 patent does not teach the use of a water-soluble monocarboxylate, a water-soluble dicarboxylate, a monocarboxylic acid and a dicarboxylic acid, and therefore this patent does not provide a medicament of the type claimed by applicant.

The examiner also rejected (in the alternative) the claims as being obvious over the '930 patent. Applicant first submits that the rejection does not comply with the dictates of MPEP § 2141 (Rev. 2, May 2004), which requires:

- (A) Consideration of the claimed invention as a whole;
- (B) Consideration of the references as a whole, and a determination that there is a suggestion to combine;
- (C) No use of impermissible hindsight; and
- (D) A showing of a reasonable expectation of success.

None of these dictates are satisfied by the rejection. Rather, the obviousness rejection seems to be employed more as a back-up of the anticipation rejection, and therefore is improper.

In any event, the examiner contends on page 3 of the office action that the differences between applicant's medicaments and those of the '930 patent are "so slight." Applicant submits that the differences are actually anything but slight, as shown in the Teschner declaration.

Applicant respectfully requests withdrawal of the anticipation and obviousness rejections based upon the '930 patent.

On pages 3-4 of the office action, the examiner repeats the rejection of claims as anticipated by U.S. Patent No. 5,561,115. Applicant respectfully traverses this rejection.


The '115 patent is discussed at paragraph 11 of the latest Teaschner declaration. As explained by Dr. Teschner, the '115 patent does not use a molecule like caprylate to replace citrate. Rather, the '115 patent teaches the use of caprylate as a protein precipitating agent early in manufacturing processes, and not as a citrate replacing agent with relatively purified products, such as late Cohn fractions containing at least 95% albumin, for example. See columns 2-4 of the '115 patent, Applicant therefore submits that the '115 patent does not anticipate the claims. Applicant respectfully requests withdrawal of the rejection.

Request

Applicant submits that the claims are in condition for allowance, and respectfully request favorable consideration to that effect. The examiner is invited to contact the undersigned at (202) 912-2000 should there be any questions.

Respectfully submitted,

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John P. Isacson
Reg. No. 33,715

HELLER EHRMAN WHITE & McAULIFFE
1666 K Street, NW, Suite 300
Washington, DC 20006-1228
(202) 912-2000 (phone)
(202) 912-2020 (fax)
Customer No. 26633